A1 CONSULTANCY & INTEGRATED SERVICES SDN BHD
No. 4-2, Jln Mutiara Melaka 2, Mutiara Melaka, Batu Berendam, 75350 Melaka, Malaysia.
Tel: (6016) 317 8158/8918, Fax: (606) 317 6748, Email: enquiry@acissb.com

Validation blues.

Most personnel from our pharmaceutical industries dreaded this issue. Validation is a mammoth task and requires considerable skill, knowledge and experience before one can even attempt to do it.

But how do we acquire all these things if we have never started to do it? Yes… that's the tricky question.

We need to undergo a training course, be trained and undergo one or two validation work before the required skill can be acquired. This is just like driving a small plane where you acquire basic technical knowledge, followed by hours of flying with an instructor before you can be licensed to pilot one.

Validation is compulsory for manufacture of pharmaceutical products. Facilities, critical utilities such as HVAC and water system, equipment, process and test methods are to be validated. Compounding this issue, the assurance of controls such as separation of penicillin and cephalosporin or clean rooms, has to proven and documented. The development of a Validation Master Plan (VMP) itself requires extensive knowledge and experience by a group of qualified and competent personnel.

To further aggravate this situation, critical processes such as sterilization and aseptic filling are to be validated on a periodic basis.

More complex is the need for cleaning validation. An extensive study has to be carried out to identify what cleaning activities need to be validated, to what extent do we need to prove cleaning efficacy and how should it be carried out.

The sad thing is this subject is seldom being given due attention by the management of most pharmaceutical industries, especially the local ones. One main obstacle for this phenomenon is cost. Conducting validation require resources, extensive man-hours and high cost.

Regardless of all these obstacles, we have no choice but to conduct validation. It is the only means to prove control of the processes carried out within the pharmaceutical sector.

There are always ways and means where validation can be initiated and conducted. Although cost remains an issue, this can be kept to a minimum. Seek assistance and help from the expert, just like what you will do if you have a medical problem. Involve your own staff in the validation exercise conducted by consultants and slowly build up your own validation team. Trust me, validation is indeed a big scope with no end; enough to justify setting up of a separate department.

Most important, start validation before the authority force you to do so!
Good luck.